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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/291,227 04/13/99 HAYEK

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HM12/0417
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EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

04/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/291,227

Applicant(s)

HAYEK, MICHAEL G.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. The request filed on January 12, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09291227 is acceptable and a CPA has been established. An action on the CPA follows.
2. Receipt of the amendments and remarks submitted January 12, 2001 is acknowledged.

Double Patenting Rejection

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,133,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '633 claim a process for enhancing immune response in animal using β -carotene. Patent '633 does not teach expressly the employment of lutein for the process. However, carotenoids, including β -carotene and lutein, are known generally to be useful for enhance immune response in animals. See column 1, lines 16-26. Therefore, it would have been prima facie obvious for a person with ordinary skill in the art at the time the claimed invention was made, to employ lutein for enhancing the immune response of a companion animals including dogs and cats.

Claim Rejections 35 U.S.C. § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 and 12 recites the broad recitation "a companion animal," and the claim also recites "dog or cat" which is the narrower statement of the range/limitation. If applicants' intention is that the companion animal is a dog or a cat, following phrase may be more clearly define the scope of the invention: "A process for enhancing immune response of [a companion animal consisting of] a dog or cat" or "A process

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for enhancing immune response of a companion animal selected from the group consisting of a dog or cat.”

Claim Rejections 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al. (CA Abstract, AN 1994:321921 of record) in view of Anon (of record), Ito et al. (US Patent 5,993,714) and Krinsky (Medline Abstract, AN 91090021) further in view of CRC Handbook of Toxicology (of record).

10. Jyonouchi et al teaches that carotenoids in general, and lutein in particular, are known to be useful in enhancing immune response in animals. See the abstract.

11. Jyonouchi et al. does not teach expressly the employment of lutein for enhancing the immune response of dog or cat, or the particular supplement for dog or cat.

12. However, Anon teaches an ailment specific dietary supplements comprising lutein. See, the title and the abstract. Ito et al. teach a animal feed comprising antioxidant selected from carotene and lutein etc. the antioxidant is in the concentration of about 0.02%. Ito further teaches method for improving the health of animal comprising feeding the animal with the antioxidant agent. The amount of the antioxidant agents is 0.02 g/kg-body weight. See, particularly, column 5, lines 16-20, and claims 8-14. Ito also teaches that the usefulness of carotenoids as food additive is for a broad range of animals including mammals and fish. See, particularly, column 6,

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lines 8-11. Krinsky teaches that it is well known that carotenoids have effect of immunoenhancement in animals. See the abstract. The CRC Handbook of Toxicology, 1995, at page 11 describes the fact that experimental animal models are known to be useful in condition that mimic human disease.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to feed supplement with lutein to a companion animal such as dog or cat.

A person of ordinary skill in the art would have been motivated to feed supplement with lutein to a companion animal such as dog or cat for immunoenhancement of the animal because lutein is known to be useful for enhancing the immune response in animals, particularly in mammals and dog and cat are mammals. An agent known generally to be useful for immunoenhancement in mammals would have been reasonably expected to be useful for immunoenhancement for dog or cat. Also, Ito shows that the biological activity of carotenoids is effective in a variety of animals, further suggesting the wide applicability of lutein in animals.

13. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (US Patent 5,993,714).

Ito et al. teach a animal feed comprising antioxidant selected from carotene and lutein etc. the antioxidant is in the concentration of about 0.02%. Ito further teaches method for improving the health of animal comprising feeding the animal with the antioxidant agent. The amount of the antioxidant agents is 0.02 g/kg-body weight. See, particularly, column 5, lines 16-20, and claims 8-14. Ito also teaches that the usefulness of carotenoids as food additive is for a broad range of animals including mammals and fish. See, particularly, column 6, lines 8-11.

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1. Ito et al. does not teach expressly to chose lutein as the active ingredients. However, the employment of lutein in the above composition and method is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388). Regarding the function limitation “for enhancing immune response,” note the instant claims are directed to effecting a biochemical pathway with old and well-known compounds. It is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant’s attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility (feeding lutein to dog or cat) for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan.

Applicants’ amendments and remarks submitted January 12, 2001 have been fully considered, but are not persuasive because of the reasons discussed below.

Regarding the remarks that “animals may be used to study the disease of humans does not provide any reasonable expectation that the administration of a dietary lutein to a mouse would also prove effective in a dog or cat,” note that mouse is an old and well-known animal models in biological studies for mammals. The fact is that lutein has been suggested to be useful for enhancing the immune response in mammals, particularly in humans and has been proved to be useful for the enhancement in mouse. It would have been reasonably expected to be useful for

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the enhancement in dog and cat, considering that mouse is genetically closer to dog and cat than to humans.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

April 11, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

